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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,546	08/24/2001	Jeffrey Errington	P02186USO	5951

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,546

Applicant(s)

ERRINGTON, JEFFREY

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-29, 32, 42-51 is/are allowed.
- 6) ☒ Claim(s) 30, 31, 33-41 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Non-Final Office action is a response to the "Amendment in Response..." filed 6 June 2003 (Paper No. 12) in reply to the Non-Final Office Action mailed 28 January 2003 (Paper No. 10). Claims 20-52 were considered in Paper No. 10. Claims 20, 28-32, 40, 41 and 51 were amended in Paper No. 12. Claims 20-52 are pending and under consideration.

Response to Amendment

Claim Objections

Objection to claim 32 is withdrawn.

Claim Rejections - 35 USC § 112

Claims 31 and 33-41 stand rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for reasons of record and herein below in the response to arguments.

Rejection of claims 28-30, 40, 41, 51 and 52 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn.

Rejection of claims 20-41 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn.

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Claim Rejections - 35 USC § 102

Rejection of claim 41 under 35 U.S.C. 102(b) as anticipated by Liao *et al.* (1997) *J. Bacteriol.* 179:1490-1496 is withdrawn.

New grounds for rejection are set forth herein below.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 31 and 33-41 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection of record, Applicant argues that the term “cell division gene” is a term known to one with skill in the art. Applicant points out that the skilled person would understand that cell division genes are a group of genes identified by mutations giving rise to a cell division defective phenotype. Applicant cites several journal articles which use the term cell division genes as evidence that “cell division gene” is a term of art and concludes, “[a]s the term cell division used in claim 31 is one known to one skilled in the art, the claimed invention is adequately described and it would be apparent to the skilled person that the inventor was in possession of the invention at the filing date” (page 11).

These arguments have been fully considered but are not found persuasive. As pointed out in the previous Office Action, to meet the written description requirement of 35 U.S.C. §112,

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first paragraph, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The specification teaches, “cell division genes include *divIB...divIC*, *divIVA*, *ftsA*, *ftsL...*, *ftsZ*, *pbpB*, as well as *spoOJ* and *spoIIIE*, and others, both known and to be discovered” (paragraph bridging pages 2 and 3). As the specification clearly indicates that the cell division gene of the claims encompasses genes that have not yet been discovered, Applicant must demonstrate that, at the time of filing, he was in possession of cell division genes that had not been discovered.

In the absence of actual reduction to practice, the written description requirement can be met by disclosure of relevant, identifying characteristics of a claimed genus (i.e., structure or other physical and/or chemical properties), by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406” MPEP §2163(3)(a)(ii). However, in the instant case, Applicant discloses only the function of a cell division gene with no disclosure of the necessary common structural attributes or features of the genus. As pointed out in the previous Office Action, “an adequate written description of a gene requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the gene itself. It is not sufficient to define gene solely by its principal biological property, i.e. it is somehow involved in cell division, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any gene with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

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Thus, claiming all genes that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997))” (bridging pages 4-5). Therefore, the claims stand rejected as lacking adequate written description for reasons of record in previous Office Actions and herein above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although claims 30 and 52 were not previously rejected on the grounds that the claimed subject matter lacked adequate written description, upon further consideration it is apparent that the claims fail to meet the written description requirement of 35 U.S.C. §112, first paragraph. The claims are directed to a method of killing or inhibiting the outgrowth of bacteria comprising contacting the bacteria with an agent identified by one of the disclosed methods. As the agent of the claims is a product by process, it reads on the agent identified by any means. Thus the claims

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are directed to a method of using an agent, wherein the agent is defined solely by its function in the disclosed methods. For reasons made of record in previous Office Actions and herein above, an adequate written description of an agent requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the agent itself. Thus, claiming a method of using all agents that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived (*Id.*).

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of *any* and *all* agents identified by the disclosed methods.

It is noted that, were the claims limited to comprising the method steps set forth in the claims from which they depend, the method would be adequately described by the specification. That is, if the claims were structured similarly to claim 41, wherein the method comprises steps for identifying an agent and further comprises steps for using the agent, the claims would no longer be directed to a method of using a product by process. Instead the claim would be directed to a process comprising steps for making and steps for using a product. As the method steps are clearly supported by the disclosure, the method as a whole would meet the written description requirement.

Allowable Subject Matter

Claims 20-29, 32 and 42-51 are allowed.

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Conclusion

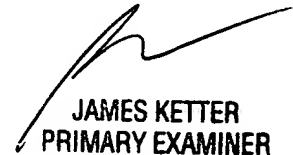
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms


JAMES KETTER
PRIMARY EXAMINER